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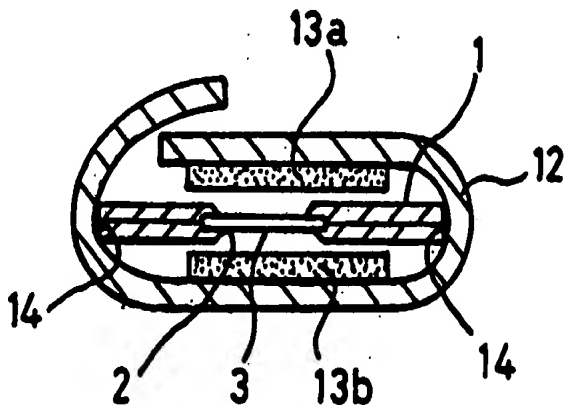
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(54) Title: NEW TEST DEVICE FOR MASS SCREENING

(57) Abstract

The invention discloses a test device comprising a substrate suitably adapted so as to provide aperture(s) wherein said aperture(s) are suitably adapted so as to support selected supportive material (3) so that fluid samples can be efficiently dispensed onto said supportive material (3) located within said apertures. Furthermore, said supportive material is further adapted so as to provide suitable guide means for checking the adequacy of the sample collected. Subsequently said test device can be placed in a suitable pouch (12) or the like, wherein said pouch (12) is adapted so as to provide desiccant properties (13) and thus to dry a fluid sample more efficiently. Eventually said test device is presented to an automated analyser for processing or the like, alternatively, said test device may be adapted so as to provide on the spot results. The device can be used for a variety of genetic, infectious or metabolic diseases and/or conditions and provides a user-friendly, cost effective efficient means of mass screening



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NEW TEST DEVICE FOR MASS SCREENING

The invention relates to a test device for use particularly but not exclusively, in automated testing apparatus and is particularly advantageous for the handling, drying, storage, transport or the like and subsequent analysis of fluid samples or the like.

Mass screening of specific subsections of the population for a range of diseases and conditions to which members of that subsection are susceptible, is a well known early warning health care measure. The aim of such screening is, principally, not to diagnose those people with the disease or condition but, rather, to reject the vast majority of the people who are clearly normal. Those who show abnormal results can then be further examined to provide a diagnosis.

A typical procedure for testing a particular cross section of the population would involve the taking of a sample of blood, urine or saliva, for example. This is usually done in a clinic, surgery or hospital where there are specialised staff ready to process, package and label such samples for transportation to a specialised laboratory for further analysis.

There are many diseases and conditions which can be screened in this way. For example; osteoporosis in post-menopausal women; in-born errors of metabolism such as phenylketonuria; metabolic disorders such as thyroid disease; clinical conditions such as neuroblastoma in children; drug and/or alcohol abuse; chromosomal abnormalities; infectious diseases; DNA profiling and the like. However, current methods and procedures for mass screening

laboratory and are, as a result, expensive.

The time consuming nature of such methods, is apparent from conventional neo-natal screening of babies. Usually, a nurse will prick the heel of, typically, a five day old infant with a needle in order to obtain a blood sample. The blood is deposited in several, usually four, predetermined locations on an absorbent test card. Each location is usually defined by a printed circle on the test card. The card also contains space for identifying details of the child under examination etc.

In order that later testing in the laboratory is carried out on approximately the same quantity of blood from each child, the nurse will normally try and ensure that within each printed circle of the card there is evenly and completely impregnated a sample of blood. This is not always possible to achieve as the child may, for example, wriggle against the paper thereby smearing blood over a greater area so that a second application is required.

Once the blood has been collected on to the absorbent test card, it must be dried prior to insertion in an envelope, or other suitable carrying means, for subsequent postage or transportation to an analysis laboratory. Air drying of samples is the method usually adopted. Typically, the nurse will move the card backwards and forwards through the air for a few minutes to facilitate drying. It is not uncommon, however, for incompletely dried samples to be placed within an envelope for transportation to the laboratory. This is to be expected given that complete drying in static air of blood samples absorbed on material, such as filter paper, can take up to four hours.

The next stage of the procedure takes place in the analysis laboratory. The

technician manually punches a hole in the blood impregnated portion of the test card, judging by eye the optimum position from which to take a sample. Typically a 3mm circle of card will be removed. This is then placed in a test tube containing a reagent into which the blood passes. The sample of card
5 is removed from the test tube leaving the blood sample ready to be further processed.

Alternatively, instead of absorbent material such as filter paper, a hydrophobic membrane is used as a supportive material on which blood samples are collected. Such a sample is dried as before and sent to a
10 laboratory for analysis. Once in the laboratory, the sample may be removed by the passing of water, or other suitable solvent, over the hydrophobic membrane so that the sample is simply washed into, for example, a test tube.

Ideally, the quantity of blood obtained for each test from each child is approximately constant. Hence the use of a standard 3mm card sample.
15 Typically, two tests are carried out on samples from each child, one for phenylketonuria and the second for thyroid disease. The absorbent test card, containing any remaining samples, is stored in case the need for repeat or further tests should arise.

Mass screening for osteoporosis in post-menopausal women is similarly time
20 consuming in that, a mid stream urine sample obtained from the patient in, for example, a bottle must be labelled and stored and later transported to a laboratory for subsequent analysis. Samples contained in bottles require specialised packing arrangements in order that these can be transported safely and securely. This sample management is an essential though repetitive and
25 manual task that is usually carried out by a dedicated staff. At present, the

samples can be obtained by patients in the privacy of their own homes, but these are then later taken, usually by hand, to a clinic for further processing.

A system for the collection of a saliva sample by a patient at home has already been developed. This system incorporates a piece of absorbent paper
5 fixed on the end of a holding stick. The paper is placed in the mouth using the holding stick. Following absorption of saliva, the paper is placed in a buffer solution contained in a small sealable bottle. The entire arrangement of paper, stick, buffer solution and bottle are then taken to a laboratory. In
10 this way, the integrity of a fluid sample obtained by a patient at home is preserved during storage and transport of the sample.

There are several problems to the use of such procedures for the mass screening of the population.

Firstly, if a test card is used, there is a risk of contamination of the samples by contact with external objects, in particular, surfaces. This can occur when
15 the test card is completely dry, but it is especially a problem when a damp card is placed in, for example, an envelope. It is impractical for a nurse in the field to wait up to four hours for the test card to be completely dry before handling it further.

The transportation of bottled samples poses particular problems in that bottles
20 have a 3-D shape and are less easy to label and send by post. In addition, there is always an inherent risk of leakage and/or breakage which not only results in the loss of the sample but can prove hazardous. Furthermore, samples stored in liquid form are inherently susceptible to deterioration and

not adequately controlled. Storage of dry samples, however, effectively freezes said samples at a point in time such that little or no deterioration occurs.

5 Secondly, the manipulations to be carried out by professional staff such as a nurse or doctor in the clinic in labelling and packaging such samples, and a technician in the laboratory in processing such samples, are of a highly repetitive and time consuming nature.

10 Thirdly, the value judgement of the laboratory technician in determining the optimum place on a test card to punch and so obtain samples, is open to error, particularly because of the repetitive nature of the work.

Fourthly, the cost of mass screening lies predominantly in the time taken to obtain, process, transport and analyse each sample from each patient. Currently, professional staff are involved in each of these stages.

15 The cost of mass screening could be significantly reduced, if people could, in the privacy of their homes, provide samples of, for example, blood, urine or saliva or any other body fluid which can be safely stored and/or sent to a central analysis centre without the risk of contamination and without the need for the involvement of professional staff.

20 Indeed, the cost of mass screening of fluid samples from a variety of sources could be reduced if such samples could be transported and analysed in the above manner. Examples of sources from which fluid samples could be taken include natural water courses, household or industrial water tanks and pipes, household pets and farm animals.

The invention of the device has elegantly and inventively overcome many of the problems associated with the prior art by providing a user friendly, effective test device comprising a substrate suitably adapted so as to provide aperture(s) wherein said apertures are suitably adapted so as to support
5 selected supportive material so that fluid sample(s) can be efficiently dispensed onto said supportive material located within said aperture(s). Furthermore, said supportive material is further adapted so as to provide suitable guide means for checking the adequacy of the sample collected. Subsequently said test device can be placed in a suitable pouch or the like,
10 wherein said pouch is adapted so as to provide desiccance properties and thus to dry a fluid sample more efficiently. Eventually said test device is presented to an automated analyzer for processing or the like.

In its broadest aspect the invention provides a mass screening test device capable of collecting multiple body fluid samples for subsequent or in situ
15 analysis.

It is therefore an object of the invention to provide a test device and carrying means or envelope to facilitate the taking of samples and the subsequent postage or transportation to a laboratory, which test device, in addition, is further adapted to be used in conjunction with automated testing apparatus.

20 It is a yet further object of the invention to provide a means for confirming the adequacy of the sample collected.

It is yet a further object of the invention to provide a reliable test device for

It is a yet further object of the invention to provide a test device for use with any body fluid and/or matter such as blood, urine, saliva, faeces or the like.

In a first aspect of the invention there is provided a test device for use in automated testing apparatus comprising supportive material mounted on at least a part of at least one substrate, which substrate is of a predetermined size and shape and comprising at least one indentation or aperture of predetermined location, size and shape over which said supportive material is at least partially positioned, whereby the positioning of a sample to be tested on said supportive material can be recognized by automated testing apparatus and said sample to be tested can be optionally removed therefrom.

In a preferred embodiment of the invention, the supportive material is spaced from an outermost surface of said substrate. Ideally, the supportive material is sandwiched between two substrates whereby, the supportive material is spaced from said outermost surface by the thickness of one substrate.

In a further preferred embodiment of the invention, there is provided a plurality of evenly spaced first indentations or apertures.

Ideally, the substrate or substrates of said test device is or are adapted to be easily manipulated by automated testing apparatus. Preferably, the test device comprises a holding means, such as ridges or holes, whereby the handling of the test device by automated apparatus is facilitated. Preferably, said first aperture is a throughbore.

In a yet further preferred embodiment of the invention at least a part of at least one surface of said support material is provided with a suitable

hydrophobic material ideally said hydrophobic material is latex or wax or the like.

In a yet further preferred embodiment of the invention said hydrophobic material is suitably configured so as to provide a guide means comprising typically a line of said hydrophobic material wherein said configuration is such that ideally a circular portion and a channel portion is defined, wherein following application of a fluid sample, fluid is allowed to permeate to an edge of said circular portion and excess fluid is directed along said channel portion.

10 In a yet further preferred embodiment of the invention said substrate is provided with at least one second aperture or indentation suitably sized and shaped and positioned, with respect to said first aperture, so as to be aligned with said channel portion of said guide means.

15 In a yet further preferred embodiment of the invention there is provided an indicator means suitably positioned with respect to said second aperture indentation, ideally said indicator means is associated with or impregnated with or cross-linked to or coated onto at least a part of a least one surface said supportive material.

20 In a yet further preferred embodiment of the invention the diameter of said guide means circular portion is greater than the diameter of the first aperture or indentation diameter and ideally is greater in diameter in the region of 1-

material or at least a part of the surface of the supportive material is adapted to efficiently and, ideally, quickly distribute a fluid sample into at least a part of the supportive material or across at least a part of the surface of the supportive material. This can be achieved by modifying physically or chemically the nature of the surface. Preferably, the supportive material is absorbent in nature, such as, filter paper. Alternatively, the supportive material may be a hydrophobic membrane.

In a yet further preferred embodiment of the invention said supportive material or at least part of the surface of said supportive material is associated or impregnated with or cross-linked to or comprises or is coated with a suitable selected material whereby a fluid sample can react directly with said material in a colourmetric and/or fluorometric and/or luminometric and/or radiometric manner whereby fluid samples may be analysed at the point in time of collection.

In a yet further preferred embodiment of the invention said test device is provided with an identification means.

In a yet further aspect of the invention, there is provided a pouch for receiving a test device, according to the invention.

Ideally, the pouch comprises a desiccant layer. Preferably, the desiccant layer comprises at least a part of at least one surface, ideally the inner surface, of the pouch.

In a further preferred embodiment of the invention, the pouch comprising a desiccant layer, is so sized and shaped so that when a test device is inserted

into the pouch, the supportive material contained in the test device is opposite or adjacent the desiccant layer. Preferably, the desiccant layer comprises silica gel. Furthermore, the pouch, at least a part of its outer surface, may comprise impervious material.

- 5 In a yet further aspect of the invention, there is provided a test kit comprising at least one test device according to the invention and at least one pouch according to the invention.

In a yet further aspect of the invention, there is provided a test kit comprising a test device, and a pouch according to the invention and a means for
10 obtaining a sample. Ideally, the means for obtaining a sample comprises a lance or blade, preferably automatic, if a blood sample is required, a pipette if a saliva sample is required, and/or, possibly, a container if a urine and/or stool sample is required. In addition, the test kit may comprise instructions and/or a bar code for identifying purposes.

- 15 Ideally, the bar code is used to indicate the identity and origin of each individual test device, the type of test to be carried out and/or the particular shape of the test device whereby automated testing apparatus can be automatically reconfigured following reading of the bar code to accommodate test devices of a variety of shapes and for a variety of tests.

- 20 In a yet further aspect of the invention there is provided a method for confirming the adequacy of a collected fluid sample comprising;

deposition portion and a channel portion;

- ii) placing said fluid sample on said deposition portion and allowing said fluid sample to fill and/or permeate into said channel portion;
- iii) collecting sufficient fluid of said sample so that said sample passes
5 over an indicator means in or associated with said channel portion;
- iv) assessing said collected fluid sample by visualisation of said indicator means and/or by automated machine analysis of said indicator means.

Particular embodiments of the invention will now be described with reference to the accompanying drawings and by way of example only.

10 In the accompanying drawings:

Figure 1a shows a plan view of a test device in accordance with the invention.

Figure 1b shows a side sectional view of a test device in accordance with the invention.

15 Figure 1c shows a plan view of a section of supportive material.

Figure 1d shows a plan view of an alternative test device in accordance with the invention.

Figure 2a shows a plan view of an alternative test device in accordance with the invention.

20 Figure 2b shows a side view of an alternative test device in accordance with the invention.

the invention.

Figure 4a shows a plan view of an alternative test device in accordance with the invention.

Figure 4b shows a side view of an alternative test device in accordance with the invention.

Figure 5a shows a plan view of an alternative test device in accordance with the invention.

Figure 5b shows a side view of an alternative test device in accordance with the invention.

Figure 6 shows a perspective view of a pouch and a test device in accordance with the invention.

Figure 7 shows a sectional view of a pouch in accordance with the invention.

Figure 8 shows a sectional view of an alternative pouch in accordance with the invention.

Particular embodiments of the invention will now be described.

Referring firstly to figure 1a, rectangular substrate 1 is clearly shown. Substrate 1 comprises four first apertures 2a, 2b, 2c and 2d of a particular size, shape and location. Substrate 1 may be made of any suitable non-absorbent material such as plastic. In this particular embodiment, the first apertures, generally labelled 2, are circular. Towards one end of the substrate 1 is provided a region for noting the identifying particulars of a patient by means of a label or otherwise. There is also provided a region 5 comprising a bar code. The bar code can be used to include several pieces of information for later use by automated testing apparatus. This information may comprise, for example, the batch number or identifying number of each individual test device, the type of test device used in its particular shape or

geometric orientation and/or a specific test or tests that are to be undertaken on the samples located within the test device. The use of a bar code containing such information facilitates the use of such test devices in automated analytical apparatus.

5 Spanning first apertures 2 are correspondingly numbered sections of supportive material labelled 3a, 3b, 3c and 3d, which supportive material sections may be a variety of shapes as shown clearly in figure 1a. For example, supportive material section 3a is generally square whereas supportive material section 3c is generally circular.

10 The supportive material located within each aperture may be absorbent or adapted to facilitate wetting of a fluid sample to the surface of the material. This can be achieved in a number of ways, for example, the use of absorbent materials, such as filter paper. Alternatively, a surface wetting agent may be applied to a part of the exposed surface of each supportive material section.

15 Turning now to figure 1b, first apertures 2 are clearly shown to be throughbores. Furthermore, substrate 1 is clearly shown to comprise an upper portion 1a and a lower portion 1b which are aligned and sandwiched together so as to provide apertures 2. Furthermore, portions 1a and 1b enclose and support the supportive material sections 3a, 3b, 3c and 3d, so that supportive
20 material spans each of the first apertures 2.

Alternatively, this may be achieved by a piece of supportive material 3 (not shown) spanning all the first apertures in substrate 1.

3c and 3d are suspended tightly across first apertures 2 (similarly a single piece of supportive material 3 may be so arranged), so as to safeguard against sections 3a, 3b, 3c and 3d (or material 3) making contact with adjacent objects. In this way, contamination of samples carried on sections 3a, 3b, 3c and 3d or (supportive material 3) is avoided. Upper or lower outermost edges 6 of first aperture 2 may be adapted to allow easy access of a finger, or other sample supporting means, to the supportive materials sections 3a, 3b, 3c and 3d (or material 3).

Referring now to Figure 1c there is shown a section of support material (3) and provided on at least one surface of said support material there is provided at least one guide means (14) wherein said guide means is configured so as to provide a circular portion (15) and a channel portion (16). The delineation of said guide means (14) is provided by a hydrophobic material such as latex or wax or the like and the configuration provides for a fluid sample to permeate across the region (15a) and upon reaching an edge of circular portion (15) fluid is directed along region (16a) of channel portion (16) so as to pass over indicator means (17). Indicator means (17) comprises an indicator printed onto the surface of said supportive material so that fluid samples passing thereover can react with said indicator means so as to illicit a change of colour, in the instance of said indicator means comprising an anhydrous copper sort or the like. Activation of said indicator means thereby assures the adequacy of the fluid sample collected. The size and shape of the guide means may be varied according to a user's requirement.

Referring now to Figure 1d, there is shown supportive material (3) as depicted in Figure 1c placed rearward of substrate (1). Additionally provided on substrate (1) is region (5) comprising a bar code. First apertures 2a

2b, 2c, 2d of substrate (1) are suitably positioned over guide means (14) so as to be aligned with the circular portion (15) of said guide means (14) so as to accommodate fluid sample collection. Channel portion (16) of guide means (14) is aligned with second apertures 2g, 2h, 2j, 2i of substrate (1) so that
5 indicator means (17) are suitably positioned so as to be observed or analysed in either a manual or an automatic manner thereby ensuring adequacy of sample collection to be directly and/or indirectly observed. In operation, fluid samples are collected on area (15a) and permeate outwards to the edge of circular portion (15a) and excess fluid is directed along channel (16) so as to
10 pass over indicator means (17) whereby fluid sample collection maybe ensured and/or checked by appropriate activation of said indicator means.

Figures 2a and 2b show an alternative embodiment of a test device. Corresponding labels refer to corresponding portions of the test device as previously described. In this embodiment, indentations 2e and 2f are located
15 in substrate 1 such that side 7 of substrate 1 is apertured or cut away at the location of indentations 2e and 2f. Corresponding supportive material 3e and 3f respectively is sandwiched between portions 1a and 1b such that the sides of indentations 2e and 2f substantially surround supportive material sections 3e and 3f. Adjacent to side 7 of substrate 1 are exposed edges 7e and 7f of
20 supportive material sections 3e and 3f respectively.

Exposure of edges 7e and 7f aid the application of, for example, a finger on which there is a blood spot, to supportive material 3e and 3f in general direction A. Furthermore, the addition of stops 8 reduce the risk of contacting edges 7e and 7f to external surfaces and, therefore, reduce the risk

Referring now to figure 3, an alternative embodiment of a test device is shown in which a plurality of first apertures 2 are disposed about a generally circular substrate 1. Means may be provided on substrate 1 for the handling of the test device in automated test apparatus. In this embodiment, a hole 9 is provided for this purpose.

Turning now to figure 4, an alternative embodiment of the test device according to the invention is shown. Features described previously have been accorded corresponding labels.

In this embodiment, supportive material 3 is attached to one side of substrate 1 by fixing means 15. Ridges 10 serve to space sections 3 from contact with external objects so reducing the risk of contamination of the samples carried on sections 3. Ridges 10 may also serve as handling means for the test device for both manual and machine handling.

In figure 5 a test device is shown. Projections 11 are used to provide spacing between material 3 and any external surfaces. The distribution of projection 11 may be optimised so that access to material 3 during sample deposition is made easier. Furthermore, in this embodiment, substrate 1 is shown to have an ergonomic shape in that sides 1c and 1d are smoothed and rounded. This adaptation is particularly useful for test devices that are to be used for the collection of, for example, a mid-stream urine sample.

It will be understood from the above that substrate 1 may be of a variety of shapes and forms and the number, size and shape of first and second apertures 2 may vary according to the requirements of a particular test or

possible arrangements for a test device. It is envisaged that the number and size of apertures will vary according to the number of tests to be carried out, the number of samples to be stored for future use and the quantity of sample required for any one test.

- 5 It will also be understood that different sized and shaped apertures may be provided on a single test device and further said test device may be subject to analysis using more than one type of test.

In a further aspect of the invention, shown in figure 6, a carrying pouch 12 is provided. Pouch 12 comprises a receiving portion 12a and a sealing
10 portion 12b. Pouch 12 may be made of, for example, any suitable impervious material.

Test device 1 is inserted into receiving portion 12a, and pouch 12 is subsequently sealed using portion 12b.

Ideally, as shown in figure 7, pouch 12 is so sized and shaped such that test
15 device 1 is securely located inside the pouch by means of edges 14 of test device 1 abutting against the inner sides of pouch 12. In the particular embodiment shown in figures 6 and 7, desiccant layers 13a and 13b are provided on the inner surfaces of pouch 12. The location of layers 13a and 13b is such that following insertion of test device 1, the layers are
20 substantially adjacent first apertures 2 and supportive material sections 3.

Alternatively, layers 13a and 13b may be arranged as afore and embedded in

Alternatively, the sides of pouch 12 may be made almost entirely from a desiccant material such that the entire test device 1 is surrounded by a desiccant layer, see figure 8. In this case, the precise relative geometry of pouch 12 and test device 1 is not so critical since all of device 1 is encompassed within a desiccant atmosphere. However, whatever the preferred arrangement, test device 1 and pouch 12 will normally be designed so that there is little relative movement between them when test device 1 is located within pouch 12.

Silica gel may be used inside layer 13 or the sides of pouch 12 in order to provide a desiccant atmosphere.

In use, a patient will be provided with a kit comprising a test device, a pouch, sample obtaining means and instructions.

In order to obtain, for example, a blood sample, a lance or blade, preferably automatic, will be provided. The usual place from which a patient obtains a sample of his or her own blood is in the fleshy part of the fingers. If this is the chosen site, the hands must be washed and then the lance or blade used to pierce the finger. Once a spot of blood has accumulated, this can be lightly touched to the supportive material, within an aperture of a test device. This is repeated at further locations on the test device until the required number of samples have been obtained.

The test device may then be inserted directly into a pouch 12 as shown in figures 6 - 8 following minimal drying time. The entire arrangement can then be sent, preferably, by post, to an analysis laboratory. The presence of the

to a dry atmosphere during transport to the laboratory so that further evaporation of moisture from the samples is encouraged. Furthermore, the test device ensures that contact between the supportive material impregnated with samples and the inner surfaces of the pouch is not possible.

- 5 Alternatively, samples of saliva may be required. In this case, a pipette may be used to obtain a quantity of saliva from the mouth. This is then applied to the supportive material at the required number of locations. The test device may then be sent to an analysis centre.

- 10 If a sample of urine is required, the patient has two options. Firstly, he may collect urine in a bottle provided with the test kit and then apply a sample of the urine to the supportive material within a number of apertures. Secondly, and alternatively, or in addition, the test device may be so adapted as to be held adjacent to the urine stream during excretion of urine. In this latter case, it may be advantageous to wait a few moments for excess droplets to fall
15 from the test device before insertion into the pouch and subsequent postage.

- Once a test device is received at an analysis laboratory, it is loaded into automatic testing apparatus by a technician. Subsequently, the apparatus, typically, reads the bar code, identifies the type and number of tests to be carried out and the geometry of the test device. In addition, the apparatus
20 locates and punches out, or otherwise removes, the required number of samples from within the corresponding number of apertures.

Fluid samples may be obtained from a variety of different sources, for example, farm animals, household pets, waterways such as rivers, streams and

for pipes, tanks and water courses may be directed towards the detection of, for example, particular strains of bacteria as well as evidence of diseases.

It can be seen that use of a test device and carrying pouch according to the invention greatly facilitates the drying, storage, transport and subsequent
5 analysis of fluid samples.

It will be understood from the above that, the use of such test kits comprising a test device and carrying pouch, by, for example, patients in the privacy of their own home and subsequent postage to an analysis laboratory will greatly reduce the demands on the time of professionals in, for example, clinics,
10 surgeries and hospitals. In this way, the cost of mass screening and in particular mass screening of specific subsections of the population is significantly decreased. Indeed, the use of mass screening for a far greater number of diseases and conditions will now be commercially viable. As a result, it can be seen that the current invention provides a significant advance
15 over the prior art.

CLAIMS

1. A test device for use in automated testing apparatus comprising supportive material mounted on at least a part of at least one substrate, which substrate is of a predetermined size and shape and comprising at least one
5 indentation or aperture of predetermined location size and shape over which said supportive material is at least partially positioned, whereby the positioning of a sample to be tested on said supportive material can be recognised by automated testing apparatus and said sample to be tested can be optionally removed therefrom.
- 10 2. A test device according to Claim 1 wherein said supportive material is spaced from an outer most surface of said substrate.
3. A test device according to Claims 1 or 2 wherein said supportive material is sandwiched between two substrates.
4. A test device according to any preceding claim wherein said substrate
15 is provided with a plurality of spaced first indentations or apertures.
5. A test device according to Claim 4 wherein said first indentations or apertures are evenly spaced thereapart.
6. A test device according to any preceding claim wherein said substrate or substrates of said test device is or are adapted to be easily manipulated by

means, whereby the handling of said test device by automated apparatus is facilitated.

8. A test device according to any preceding claim wherein said first aperture is a throughbore.

5 9. A test device according to any preceding claim wherein at least a part of at least one surface of said support material is provided with a suitable hydrophobic material.

10. A test device according to Claim 9 wherein said hydrophobic material is latex or wax or the like.

10 11. A test device according to Claim 9 or 10 wherein said hydrophobic material is suitably configured so as to provide a guide means.

12. A test device according to Claim 11 wherein said guide means configuration defines a circular portion and a channel portion.

15 13. A test device according to any preceding claim wherein said substrate is provided with at least one second aperture or indentation suitably sized and shaped and positioned, with respect to said first aperture, so as to be aligned with said channel portion of said guide means.

14. A test device according to Claim 13 comprising an indicator means suitably positioned with respect to said second aperture or indentation.

20 15. A test device according to Claim 14 wherein said indicator means is

associated with, or impregnated with, or cross-linked to, or coated onto, at least a part of at least one surface of said supportive material.

16. A test device according to Claims 12 to 15 wherein the diameter of said guide means circular portion is greater than the diameter of the first aperture or indentation.

17. A test device according to Claim 16 wherein said diameter is greater in the region of 1 to 5mm.

18. A test device according to any preceding claim wherein said supportive material, or at least a part of said supportive material, is adapted to efficiently and quickly distribute a fluid sample into at least a part of the supportive material or across at least part of said supportive material.

19. A test device according to any preceding claim wherein said supportive material is absorbent in nature.

20. A test device according to any preceding claim wherein said supportive material comprises a hydrophobic membrane.

21. A test device according to any preceding claim wherein said supportive material is provided with colourmetric and/or fluorometric and/or luminometric and/or radiometric indicator means whereby fluid samples may be analysed.

22. A test device according to any preceding claims wherein said device

23. A pouch for receiving a test device according to any preceding claim.
24. A pouch according to Claim 23 wherein said pouch comprises a desiccant.
25. A pouch according to Claim 24 wherein said desiccant comprises at
5 least a part of at least one surface of said pouch.
26. A pouch according to Claims 24 to 25 wherein said desiccant is provided on an inner surface of said pouch.
27. A pouch according to Claims 24 to 26 wherein said pouch comprises
10 a desiccant which is so sized and shaped so that when the test device is inserted into the pouch the supportive material contained in the test device is opposite, or adjacent, the desiccant.
28. A pouch according to Claims 24 to 27 wherein said desiccant comprises silica gel.
29. A pouch according to Claims 23 to 27 wherein at least a part of its
15 outer surface is made from impervious material.
30. A test kit comprising at least one test device according to Claims 1 to 27 and at least one pouch according to Claims 23 to 29.

32. A test kit according to Claim 31 wherein said means for obtaining a sample comprises a lance or blade, if a blood sample is required, a pipette if a saliva sample is required, and/or a container if a urine and/or stool sample is required.

5 33. A test kit according to Claims 30 to 32 comprising instructions and/or a barcode for identifying purposes.

34. A test kit according to Claim 33 wherein an identification means is provided to indicate the identity and origin of each individual test device, the type of test to be carried out and/or the particular shape of the test device
10 whereby automated testing apparatus can be automatically re-configured following reading of the identification means to accommodate test devices of a variety of shapes and for a variety of tests.

35. A method for confirming the adequacy of a collected fluid sample using the test device according to any preceding claim, comprising;

15 (i) providing a supportive material on which there is imprinted a suitable hydrophobic material which defines a guide means comprising a deposition portion and a channel portion;

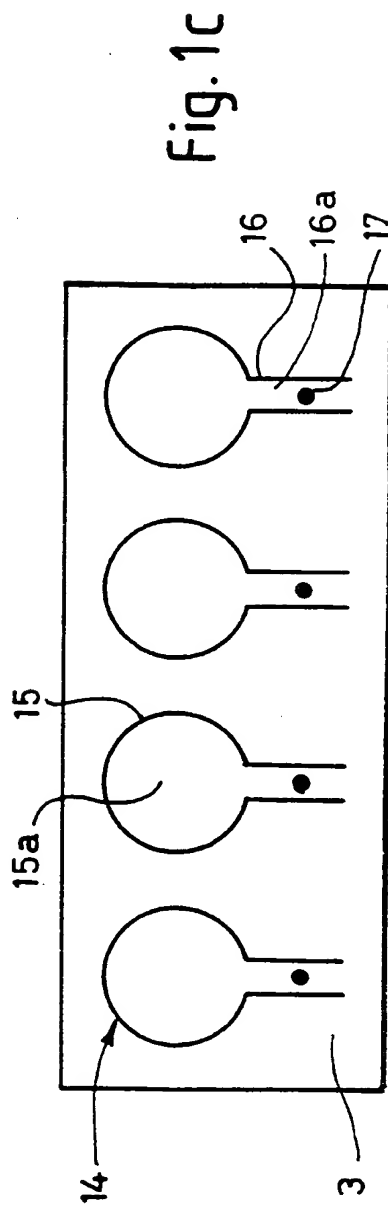
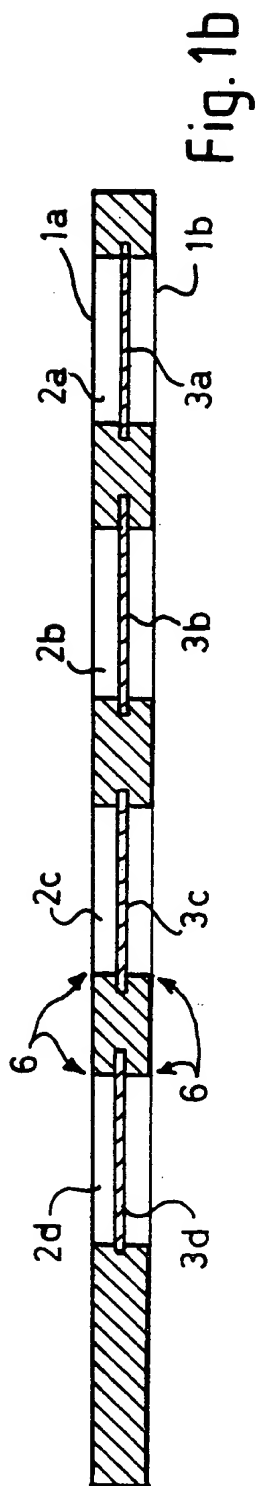
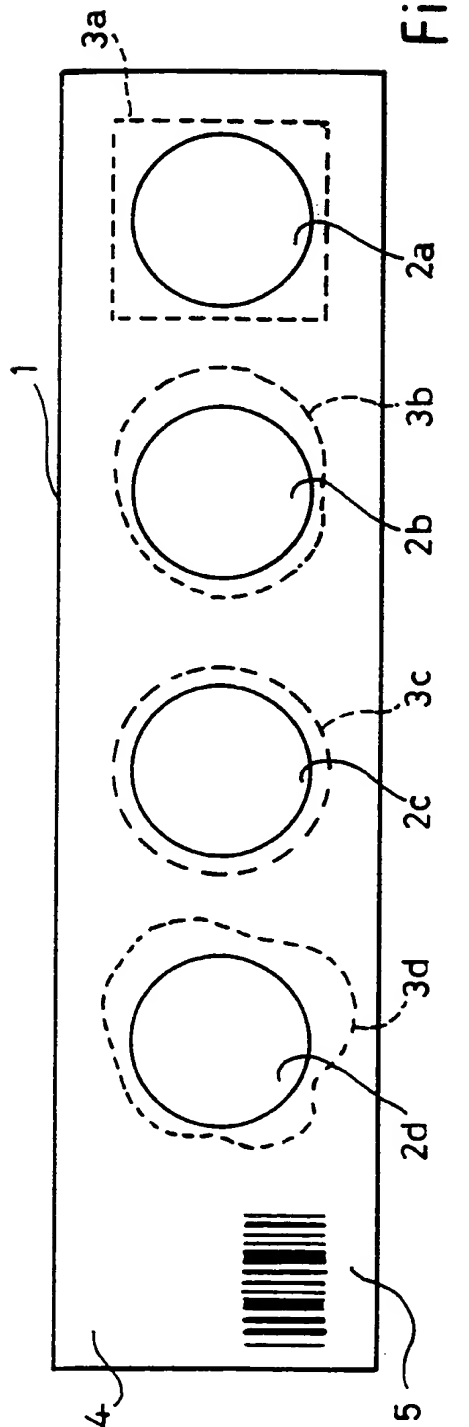
(ii) placing said fluid sample on said deposition portion and allowing said fluid sample to fill and/or permeate into said
20 channel portion;

(iii) collecting sufficient fluid of said sample so that said sample passes over an indicator means in or associated with said

channel portion;

- (iv) assessing said collected fluid sample by visualisation of said indicator means and/or by automated machine analysis of said indicator means.

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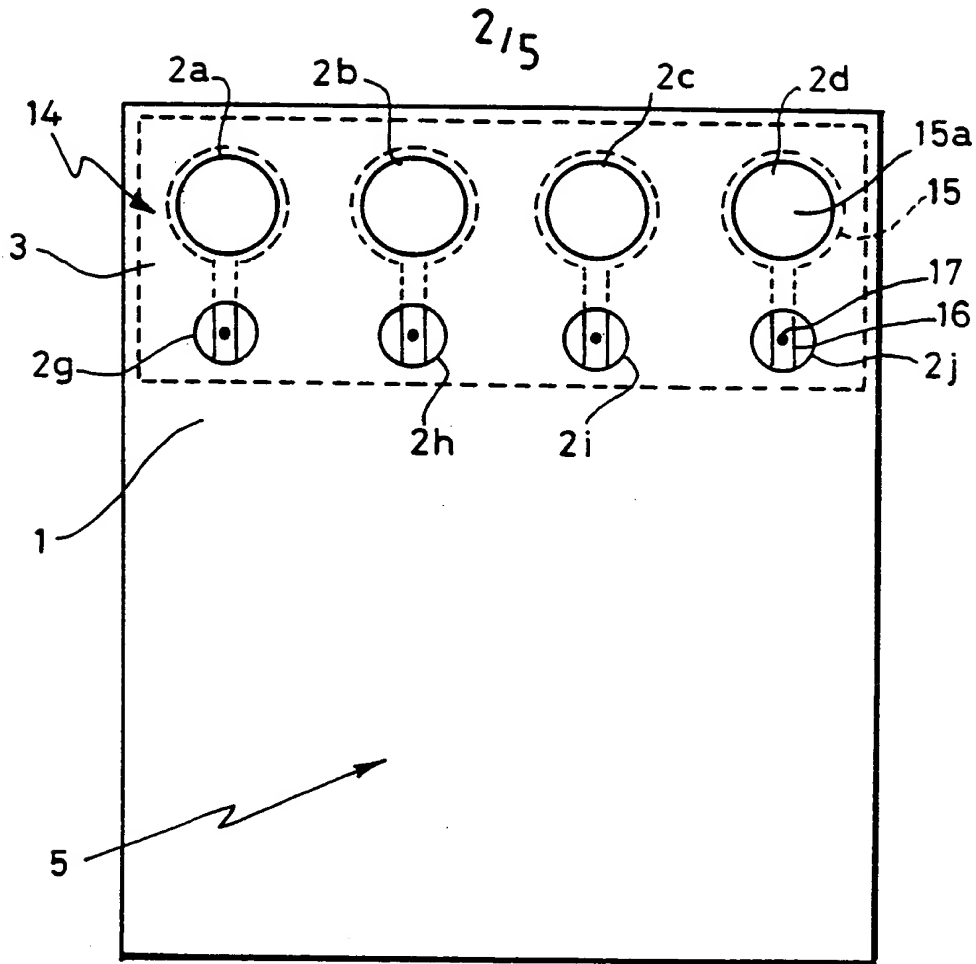


Fig. 1d

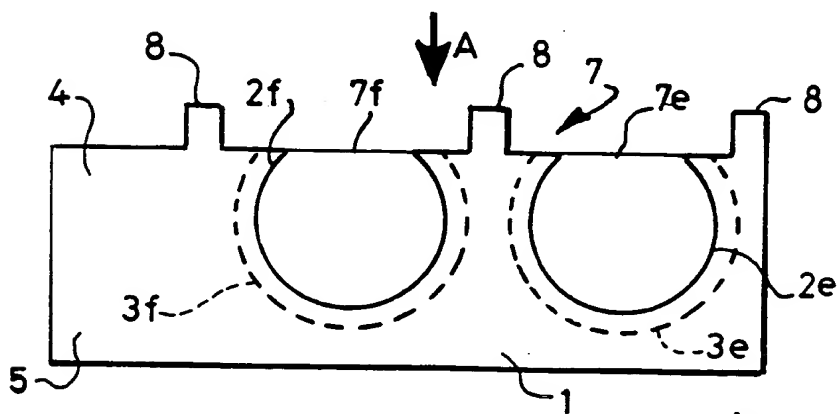


Fig. 2a

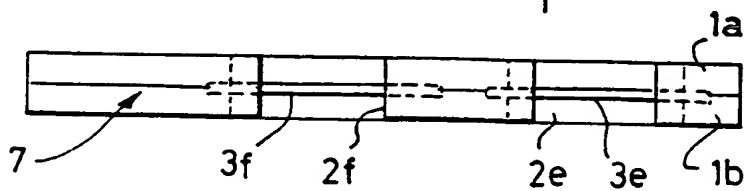


Fig. 2b

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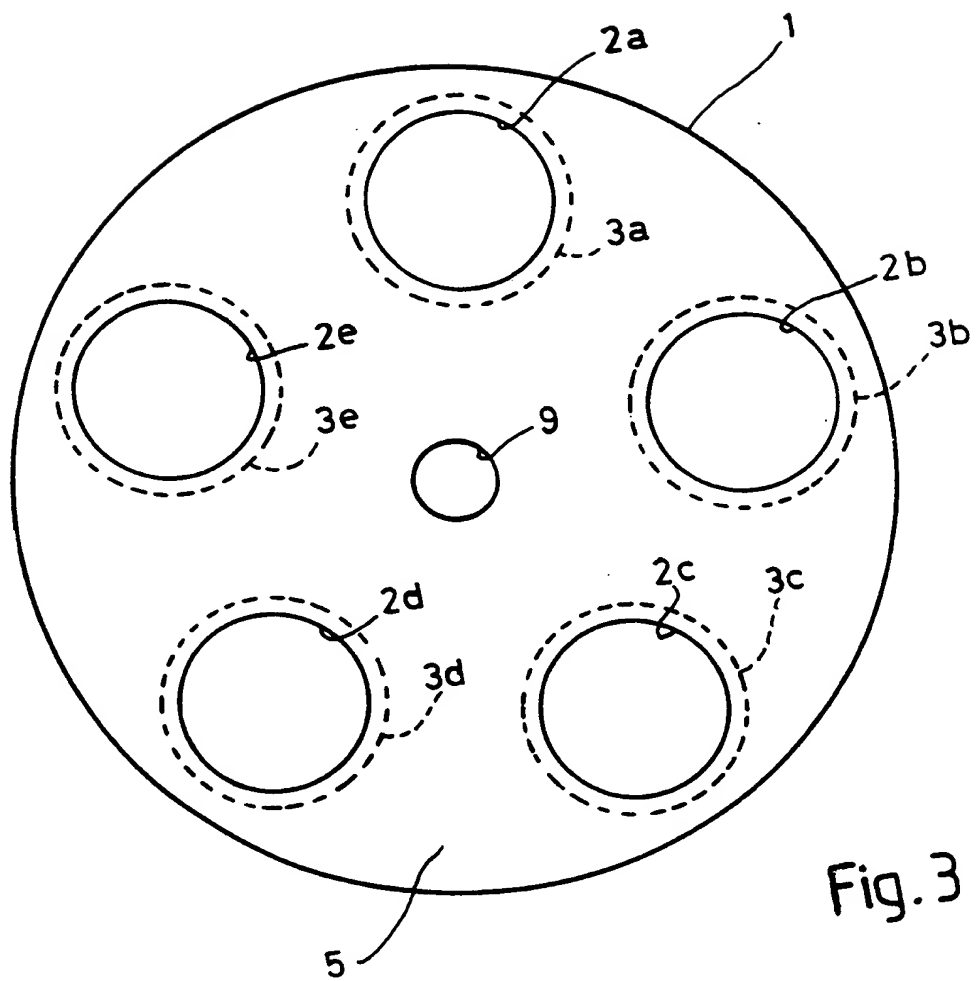


Fig. 3

4/5

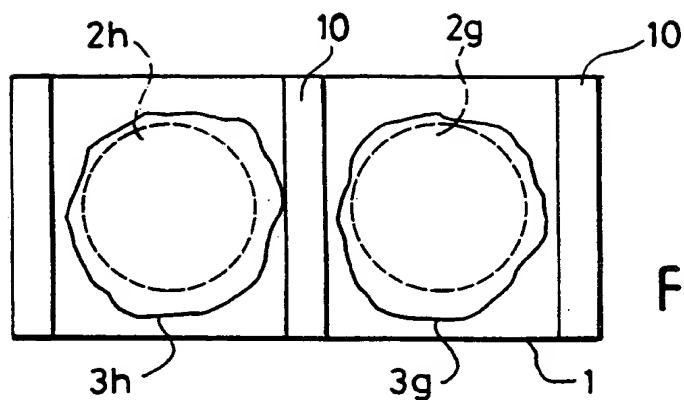


Fig. 4a

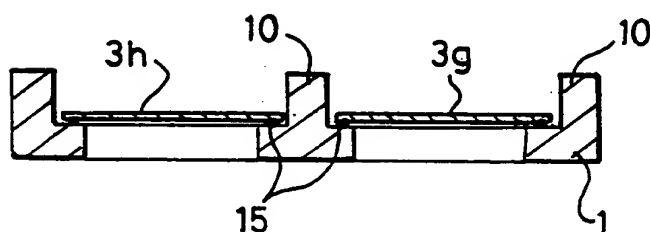


Fig. 4b

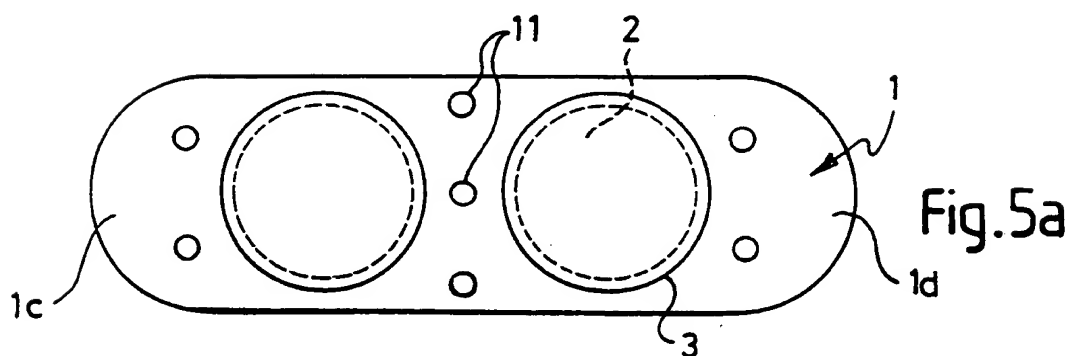


Fig. 5a

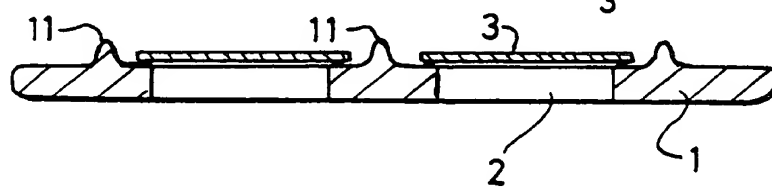
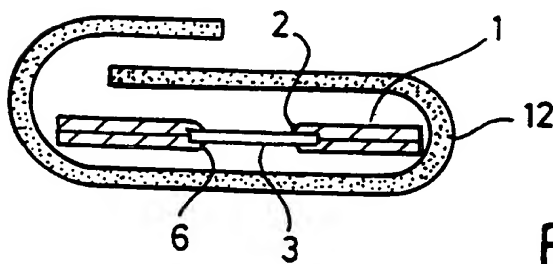
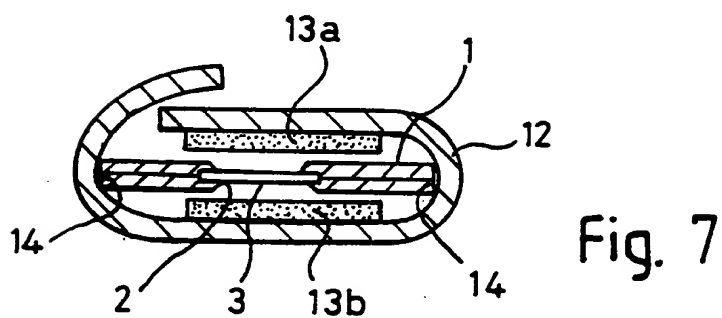
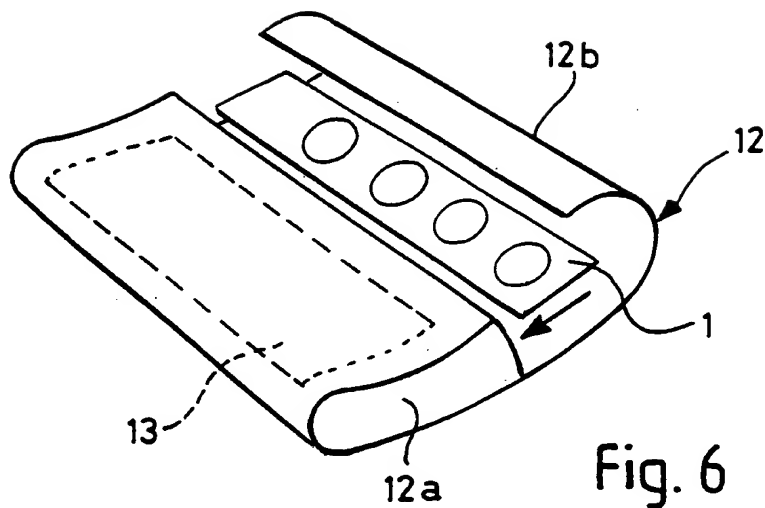


Fig. 5b

5/5



INTERNATIONAL SEARCH REPORT

Internat. Application No
PCT/GB 97/01939

A CLASSIFICATION OF SUBJECT MATTER
IPC 6 B01L3/00 A61B10/00 G01N33/52

According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B01L G01N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category Citation of document, with indication, where appropriate, of the relevant passages

X

Y

A

Y

EP 0 583 078 A (WALLAC OY) 16 February 1994
see page 2, line 15 - line 52

see page 3, line 4 - line 10
see page 3, line 45 - line 50
see page 4, line 25 - line 30
see page 5, line 36 - page 6, line 38;
figures 3-10

US 5 520 041 A (HASWELL JAMES S) 28 May 1996
see column 3, line 60 - column 4, line 42
see column 5, line 12 - line 20
see column 6, line 59 - column 7, line 14

Relevant to claim No.

1-8, 18,
19, 22
9-11, 20,
21, 23,
24, 28-34

17

23, 24,
28-34



Further documents are listed in the continuation of box C.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed



Patent family members are listed in annex.

"T" later document published after the international or priority date and not in conflict with the app cited to understand the principle or theory un invention

"X" document of particular relevance; the claimed cannot be considered novel or cannot be co involve an inventive step when the docume

"Y" document of particular relevance; the claim cannot be considered to involve an invent document is combined with one or more c ments, such combination being obvious t in the art.

"g" document member of the same patent fa

Date of mailing of the international sear

01/12/1997

Authorized officer

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 97/01939

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3 418 083 A (REY HANS-GEORG ET AL) 24 December 1968 see column 1, line 51 - column 2, line 42 ---	20
Y	US 2 129 754 A (YAGODA) 13 September 1938 see page 1, column 1, line 40 - column 2, line 21 ---	9-11,21, 35
Y	US 4 846 182 A (FOGT ERIC J ET AL) 11 July 1989 see column 2, line 49 - line 68 see column 3, line 28 - line 46 see column 3, line 55 - column 4, line 34 ---	35
A		12-16,21
A	WO 93 11434 A (OSBORN LAB INC) 10 June 1993 see page 10, line 1 - page 11, line 33 see page 13, line 1 - line 11 see page 51, line 10 - line 15 ---	14,35
A		11,12
A	US 4 622 207 A (WANG JOSEPH Y) 11 November 1986 see column 3, line 8 - line 60 see column 5, line 49 - column 6, line 9 ---	9,20
A	US 5 409 664 A (ALLEN MICHAEL P) 25 April 1995 see column 4, line 37 - line 41 see column 5, line 24 - line 35 see column 6, line 20 - line 60	11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 97/01939

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0583078 A	16-02-94	DE 69308957 D	24-04-97
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		EP 0625268 A	23-11-94

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		AU 4918885 A	19-06-86
		CA 1239571 A	26-07-88
		EP 0185982 A	02-07-86
		JP 61153566 A	12-07-86

CLAIMS

1. A test device for use in automated testing apparatus comprising supportive material mounted on at least a part of at least one substrate, which substrate is of a predetermined size and shape and comprising at least one indentation or aperture of predetermined location size and shape over which said supportive material is at least partially positioned, whereby the positioning of a sample to be tested on said supportive material can be recognised by automated testing apparatus and said sample to be tested can be optionally removed therefrom.

2. A test device according to Claim 1 wherein said supportive material is spaced from an outer most surface of said substrate.

3. A test device according to Claims 1 or 2 wherein said supportive material is sandwiched between two substrates.

4. A test device according to any preceding claim wherein said substrate is provided with a plurality of spaced first indentations or apertures.

5. A test device according to Claim 4 wherein said first indentations or apertures are evenly spaced thereapart.

6. A test device according to any preceding claim wherein said substrate or substrates of said test device is or are adapted to be easily manipulated by automated testing apparatus.

7. A test device according to any preceding claim comprising a holding

*Replaced by
Article 34 Proceedure*

means, whereby the handling of said test device by automated apparatus is facilitated.

8. A test device according to any preceding claim wherein said first aperture is a throughbore.

5 9. A test device according to any preceding claim wherein at least a part of at least one surface of said support material is provided with a suitable hydrophobic material.

10. A test device according to Claim 9 wherein said hydrophobic material is latex or wax or the like.

10 11. A test device according to Claim 9 or 10 wherein said hydrophobic material is suitably configured so as to provide a guide means.

12. A test device according to Claim 11 wherein said guide means configuration defines a circular portion and a channel portion.

15 13. A test device according to any preceding claim wherein said substrate is provided with at least one second aperture or indentation suitably sized and shaped and positioned, with respect to said first aperture, so as to be aligned with said channel portion of said guide means.

14. A test device according to Claim 13 comprising an indicator means suitably positioned with respect to said second aperture or indentation.

20 15. A test device according to Claim 14 wherein said indicator means is

associated with, or impregnated with, or cross-linked to, or coated onto, at least a part of at least one surface of said supportive material.

16. A test device according to Claims 12 to 15 wherein the diameter of said guide means circular portion is greater than the diameter of the first aperture or indentation.

17. A test device according to Claim 16 wherein said diameter is greater in the region of 1 to 5mm.

18. A test device according to any preceding claim wherein said supportive material, or at least a part of said supportive material, is adapted to efficiently and quickly distribute a fluid sample into at least a part of the supportive material or across at least part of said supportive material.

19. A test device according to any preceding claim wherein said supportive material is absorbent in nature.

20. A test device according to any preceding claim wherein said supportive material comprises a hydrophobic membrane.

21. A test device according to any preceding claim wherein said supportive material is provided with colourmetric and/or fluorometric and/or luminometric and/or radiometric indicator means whereby fluid samples may be analysed.

22. A test device according to any preceding claims wherein said device is provided with identification means.

24

23. A pouch for receiving a test device according to any preceding claim.

24. A pouch according to Claim 23 wherein said pouch comprises a desiccant.

25. A pouch according to Claim 24 wherein said desiccant comprises at least a part of at least one surface of said pouch.

26. A pouch according to Claims 24 to 25 wherein said desiccant is provided on an inner surface of said pouch.

27. A pouch according to Claims 24 to 26 wherein said pouch comprises a desiccant which is so sized and shaped so that when the test device is inserted into the pouch the supportive material contained in the test device is opposite, or adjacent, the desiccant.

28. A pouch according to Claims 24 to 27 wherein said desiccant comprises silica gel.

29. A pouch according to Claims 23 to 27 wherein at least a part of its outer surface is made from impervious material.

30. A test kit comprising at least one test device according to Claims 1 to 27 and at least one pouch according to Claims 23 to 29.

31. A test kit according to Claim 30 comprising a means for obtaining a sample

32. A test kit according to Claim 31 wherein said means for obtaining a sample comprises a lance or blade, if a blood sample is required, a pipette if a saliva sample is required, and/or a container if a urine and/or stool sample is required.

5 33. A test kit according to Claims 30 to 32 comprising instructions and/or a barcode for identifying purposes.

34. A test kit according to Claim 33 wherein an identification means is provided to indicate the identity and origin of each individual test device, the type of test to be carried out and/or the particular shape of the test device
10 whereby automated testing apparatus can be automatically re-configured following reading of the identification means to accommodate test devices of a variety of shapes and for a variety of tests.

35. A method for confirming the adequacy of a collected fluid sample using the test device according to any preceding claim, comprising;

15 (i) providing a supportive material on which there is imprinted a suitable hydrophobic material which defines a guide means comprising a deposition portion and a channel portion;

(ii) placing said fluid sample on said deposition portion and allowing said fluid sample to fill and/or permeate into said
20 channel portion;

(iii) collecting sufficient fluid of said sample so that said sample passes over an indicator means in or associated with said

channel portion;

- (iv) assessing said collected fluid sample by visualisation of said indicator means and/or by automated machine analysis of said indicator means.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FP2130	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 97/ 01939	International filing date (day/month/year) 16/07/1997	(Earliest) Priority Date (day/month/year) 17/07/1996
Applicant CUNNINGHAM, Robert William		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).
2. ☐ Unity of invention is lacking (see Box II).
3. ☐ The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
 - ☐ filed with the international application.
 - ☐ furnished by the applicant separately from the international application,
 - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - ☐ Transcribed by this Authority
4. With regard to the title, ☒ the text is approved as submitted by the applicant
 - ☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,
 - ☐ the text is approved as submitted by the applicant
 - ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 97/01939

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The invention discloses a test device comprising a substrate suitably adapted so as to provide aperture(s) wherein said aperture(s) are suitably adapted so as to support selected supportive material (3) so that fluid samples can be efficiently dispensed onto said supportive material (3) located within said apertures. Furthermore, said supportive material is further adapted so as to provide suitable guide means for checking the adequacy of the sample collected. Subsequently said test device can be placed in a suitable pouch (12) or the like, wherein said pouch (12) is adapted so as to provide desiccant properties (13) and thus to dry a fluid sample more efficiently. Eventually said test device is presented to an automated analyser for processing or the like, alternatively, said test device may be adapted so as to provide on the spot results. The device can be used for a variety of genetic, infectious or metabolic diseases and/or conditions and provides a user-friendly, cost effective, efficient means of mass screening.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 97/01939

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 B01L3/00 A61B10/00 G01N33/52

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 B01L G01N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 583 078 A (WALLAC OY) 16 February 1994	1-8, 18, 19, 22
Y	see page 2, line 15 - line 52	9-11, 20, 21, 23, 24, 28-34
A	see page 3, line 4 - line 10 see page 3, line 45 - line 50 see page 4, line 25 - line 30 see page 5, line 36 - page 6, line 38; figures 3-10	17
Y	US 5 520 041 A (HASWELL JAMES S) 28 May 1996 see column 3, line 60 - column 4, line 42 see column 5, line 12 - line 20 see column 6, line 59 - column 7, line 14	23, 24, 28-34



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

20 November 1997

Date of mailing of the international search report

01/12/1997

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Hocquet, A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 97/01939

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3 418 083 A (REY HANS-GEORG ET AL) 24 December 1968 see column 1, line 51 - column 2, line 42 ---	20
Y	US 2 129 754 A (YAGODA) 13 September 1938 see page 1, column 1, line 40 - column 2, line 21 ---	9-11,21, 35
Y	US 4 846 182 A (FOGT ERIC J ET AL) 11 July 1989 see column 2, line 49 - line 68 see column 3, line 28 - line 46 see column 3, line 55 - column 4, line 34 ---	35 12-16,21
A	WO 93 11434 A (OSBORN LAB INC) 10 June 1993 see page 10, line 1 - page 11, line 33 see page 13, line 1 - line 11 see page 51, line 10 - line 15 ---	14,35 11,12
A	US 4 622 207 A (WANG JOSEPH Y) 11 November 1986 see column 3, line 8 - line 60 see column 5, line 49 - column 6, line 9 ---	9,20
A	US 5 409 664 A (ALLEN MICHAEL P) 25 April 1995 see column 4, line 37 - line 41 see column 5, line 24 - line 35 see column 6, line 29 - line 68 -----	11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 97/01939

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0583078 A	16-02-94	DE 69308957 D DE 69308957 T US 5460057 A	24-04-97 04-09-97 24-10-95
US 5520041 A	28-05-96	NONE	
US 3418083 A	24-12-68	DE 1598048 A BE 681364 A CH 458793 A FR 1484845 A GB 1083683 A LU 51140 A NL 129843 C NL 6606814 A SE 326318 B	12-06-69 21-11-66 20-09-67 18-07-66 21-11-66 20-07-70
US 2129754 A	13-09-38	NONE	
US 4846182 A	11-07-89	US 4444193 A CA 1217698 A EP 0083941 A	24-04-84 07-02-87 20-07-83
WO 9311434 A	10-06-93	US 5334502 A CA 2121361 A,C EP 0625268 A	02-08-94 10-06-93 23-11-94
US 4622207 A	11-11-86	AU 558584 B AU 4918885 A CA 1239571 A EP 0185982 A JP 61153566 A	05-02-87 19-06-86 26-07-88 02-07-86 12-07-86
US 5409664 A	25-04-95	AU 7801694 A WO 9509357 A	18-04-95 06-04-95

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

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Crystal Plaza 2
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in its capacity as elected Office

Date of mailing (day/month/year) 03 March 1998 (03.03.98)	
International application No. PCT/GB97/01939	Applicant's or agent's file reference FP 2130
International filing date (day/month/year) 16 July 1997 (16.07.97)	Priority date (day/month/year) 17 July 1996 (17.07.96)
Applicant CUNNINGHAM, Robert, William	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

10 February 1998 (10.02.98)

☐ in a notice effecting later election filed with the International Bureau on:
2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Nicola Wolff Telephone No.: (41-22) 338.83.38
---	--

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MARKGRAAF PATENTS LIMITED
The Crescent
54 Blossom Street
York YO2 2AP
ROYAUME-UNI

Date of mailing (day/month/year) 03 March 1998 (03.03.98)	
Applicant's or agent's file reference FP 2130	IMPORTANT NOTIFICATION
International application No. PCT/GB97/01939	International filing date (day/month/year) 16 July 1997 (16.07.97)

1. The following indications appeared on record concerning:

☐ the applicant
 ☐ the inventor
 ☒ the agent
 ☐ the common representative

Name and Address

WILLIAM JONES (YORK)
The Crescent
54 Blossom Street
York YO2 2AP
United Kingdom

State of Nationality

State of Residence

Telephone No.

01904 610586

Facsimile No.

01904 610909

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
 ☒ the name
 ☐ the address
 ☐ the nationality
 ☐ the residence

Name and Address

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3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
 ☐ the designated Offices concerned
☐ the International Searching Authority
 ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority
 ☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 GENEVE 20

Authorized officer

Nicola Wolff

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP 2130	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
International application No. PCT/GB97/01939	International filing date (day/month/year) 16/07/1997	Priority date (day/month/year) 17/07/1996	
International Patent Classification (IPC) or national classification and IPC B01L3/00			
Applicant CUNNINGHAM, Robert William			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 10/02/1998	Date of completion of this report 1 8. 09. 98
Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Chevallier, F Telephone No. (+49-89) 2399-8612 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB97/01939

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-20 as originally filed

Claims, No.:

1-31 as received on 05/08/1998 with letter of 03/08/1998

Drawings, sheets:

1/5-5/5 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB97/01939

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-31
	No: Claims
Inventive step (IS)	Yes: Claims 1-31
	No: Claims
Industrial applicability (IA)	Yes: Claims 1-31
	No: Claims

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB97/01939

V. Statement under article 35.2) PCT.

The present statement is made in spite of the fact that the set of claims lacks clarity (see VIII below). In particular, the statement concerning claims 19 to 30 concerns an association pouch **and** test device (see VIII.6 below).

EP-A-0 583 078 (D1) may be seen as the closest prior art. This known art does not show guide means as claimed and, in particular, an indicator means in a channel portion of a guide means so as to provide a measure of the adequacy of the sample collected.

It is not considered that the remaining available prior art could lead a skilled person to modify the test device known from D1 to arrive at the claimed test device of the application. In particular, US-A-2 129 754 (D2) and WO-A-93 11434 (D3), which are cited in the search report in relation to "guide means" and "indicator means", disclose two alternatives to position adequately a sample on a supportive material (guide means **or** indicator means). In the view of the authorised Officer, this teaching cannot lead a skilled person to think at a **combination** of guide means **and** indicator means, a fortiori to lead such a skilled person to modify the device known from D1 to introduce such a combination. The same applies of course to dependent claims 2-18 because they contain all features of claim 1 and to an **association** test device as claimed **and** pouch as claimed. However should claims 19-25 remain as they are in any regional phase, a novelty objection should be raised for the reasons mentioned under VIII.6 below.

VIII. Observations.

1. Figures 1a and 1b in the application are described as an embodiment of the invention. However, this embodiment does not exhibit all features of claim 1 and is unable to perform the method of claim 31.
2. Claims 1 and 31.

Any part of **any** device is "of a predetermined location, size and shape", so that no clear limitation may be seen in this respect.

In view of the fact that PCT Article 35.2 requires that "in claims 1 and 31 should read

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB97/01939

"consisting of" to make clear that "characterized by" concern the features of the guide means and not the two part form of the claim in the sense of this rule.

3. Claims 7, 8

There is no support in the application for any technical effect related to the provision of an hydrophobic material which does not form the claimed guide means.

A **suitable** hydrophobic material does not define any clear selection among all possible hydrophobic materials.

4. Claims 11

Which possibility not included in claim 11 (dependent on 1) is covered by claim 1 ?

5. Claim 14.

"adapted to efficiently and quickly distribute..." cannot clearly define a part of a device.

6. Claims 19-25.

Claims 19-25 defining a pouch as such (claim 19 is an independent claim), the claimed pouch cannot differ from **any** pouch by the feature "is of a size and shape that correspond... to any preceding claim" because the test device as claimed may be of **any** size and shape. In any case, pouches of any size are known and the application does not seem to support pouches for which the shape could be seen as inventive.

7. In all claims, reference signs from the drawings would definitely increase the

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MARKGRAAF PATENTS LIMITED
THE CRESCENT
54 Blossom Street
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North Yorkshire YO2 2AP
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

18.09.98

Applicant's or agent's file reference
FP 2130

IMPORTANT NOTIFICATION

International application No.

PCT/GB97/01939

International filing date (day/month/year)

16/07/1997

Priority date (day/month/year)

17/07/1996

Applicant

CUNNINGHAM, Robert William

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP 2130	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
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- VI ☐ Certain documents cited
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Date of submission of the demand 10/02/1998	Date of completion of this report 1 8. 09. 98
Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523858 epmu d Fax: (+49-89) 2399-4465	Authorized officer Chevallier, F Telephone No. (+49-89) 2399-8612 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB97/01939

I. Basis of the report

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3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application N . PCT/GB97/01939

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Yes: Claims 1-31
	No: Claims
Inventive step (IS)	Yes: Claims 1-31
	No: Claims
Industrial applicability (IA)	Yes: Claims 1-31
	No: Claims

2. Citations and explanations**see separate sheet****VIII. Certain observations on the International application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB97/01939

V. Statement under article 35.2) PCT.

The present statement is made in spite of the fact that the set of claims lacks clarity (see VIII below). In particular, the statement concerning claims 19 to 30 concerns an association pouch **and** test device (see VIII.6 below).

EP-A-0 583 078 (D1) may be seen as the closest prior art. This known art does not show guide means as claimed and, in particular, an indicator means in a channel portion of a guide means so as to provide a measure of the adequacy of the sample collected.

It is not considered that the remaining available prior art could lead a skilled person to modify the test device known from D1 to arrive at the claimed test device of the application. In particular, US-A-2 129 754 (D2) and WO-A-93 11434 (D3), which are cited in the search report in relation to "guide means" and "indicator means", disclose two alternatives to position adequately a sample on a supportive material (guide means **or** indicator means). In the view of the authorised Officer, this teaching cannot lead a skilled person to think at a **combination** of guide means **and** indicator means, a fortiori to lead such a skilled person to modify the device known from D1 to introduce such a combination. The same applies of course to dependent claims 2-18 because they contain all features of claim 1 and to an **association** test device as claimed **and** pouch as claimed. However should claims 19-25 remain as they are in any regional phase, a novelty objection should be raised for the reasons mentioned under VIII.6 below.

VIII. Observations.

1. Figures 1a and 1b in the application are described as an embodiment of the invention. However, this embodiment does not exhibit all features of claim 1 and is unable to perform the method of claim 31.
2. Claims 1 and 31.

Any part of **any** device is "of a predetermined location, size and shape", so that no clear limitation may be seen in this respect.

In view of rule 6.3b) PCT, "characterized by" in claims 1 and 31 should read

INTERNATIONAL PRELIMINARY

International application No. PCT/GB97/01939

EXAMINATION REPORT - SEPARATE SHEET

"consisting of" to make clear that "characterized by" concern the features of the guide means and not the two part form of the claim in the sense of this rule.

3. Claims 7, 8

There is no support in the application for any technical effect related to the provision of an hydrophobic material which does not form the claimed guide means.

A **suitable** hydrophobic material does not define any clear selection among all possible hydrophobic materials.

4. Claims 11

Which possibility not included in claim 11 (dependent on 1) is covered by claim 1 ?

5. Claim 14.

"adapted to efficiently and quickly distribute..." cannot clearly define a part of a device.

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Claims 19-25 defining a pouch as such (claim 19 is an independent claim), the claimed pouch cannot differ from **any** pouch by the feature "is of a size and shape that correspond... to any preceding claim" because the test device as claimed may be of any size and shape. In any case, pouches of any size are known and the application does not seem to support pouches for which the shape could be seen as inventive.

7. In all claims, reference signs from the drawings would definitely increase the intelligibility of the claims.

CLAIMS

1. A test device for use in automated testing apparatus comprising: a substrate of predetermined size and shape, so as to facilitate handling by said automated testing apparatus, and including at least one indentation or aperture wherein said indentation or aperture is of a predetermined location, size and shape with respect to said automatic testing apparatus; and further comprising supportative material mounted on at least a part of said substrate so as to be at least partially positioned over said indentation or aperture; and wherein said supportative material comprises a guide means characterised by a sample deposition portion and attached thereto a channel portion including an indicator means; whereby the positioning of a sample to be tested on said sample deposition portion of said supportive material results in said sample travelling along said channel portion and interacting with said indicator means so as to provide a measure of the adequacy of the fluid sample collected.

2. A test device according to Claim 1 wherein said supportive material is spaced from an outer most surface of said substrate.

3. A test device according to Claims 1 or 2 wherein said supportive material is sandwiched between two substrates.

4. A test device according to any preceding claim wherein said substrate is provided with a plurality of spaced first indentations or apertures.

6. A test device according to any preceding claim comprising a holding means, whereby the handling of said test device by automated apparatus is facilitated.

7. A test device according to any preceding claim wherein at least a part of at least one surface of said supportive material is provided with a suitable hydrophobic material.

8. A test device according to Claim 7 wherein said hydrophobic material is latex or wax or the like.

9. A test device according to any preceding claim wherein said substrate is provided with at least one second indentation or aperture suitably sized and shaped and positioned, with respect to said first aperture, so as to be aligned with said channel portion of said guide means.

10. A test device according to Claim 9 wherein said indentation or aperture is positioned so as to be aligned with said indicator means.

11. A test device according to any preceding Claim wherein said indicator means is associated with, or impregnated with, or cross-linked to, or coated onto, at least a part of at least one surface of said supportive material.

12. A test device according to any preceding Claim wherein said sample deposition portion is circular and the diameter of same is greater than the diameter of the first indentation or aperture.

13. A test device according to Claim 12 wherein said sample deposition diameter is greater or in the region of 1 to 5mm.

14. A test device according to any preceding claim wherein said supportive material, or at least a part of said supportive material, is adapted to efficiently and quickly distribute a fluid sample into at least a part of the supportive material or across at least part of said supportive material.

15. A test device according to any preceding claim wherein said supportive material is absorbent in nature.

16. A test device according to any preceding claim wherein said supportive material comprises a hydrophobic membrane.

17. A test device according to any preceding claim wherein said supportive material is provided with colourmetric and/or fluorometric and/or luminometric and/or radiometric indicator means whereby fluid samples may be analysed.

18. A test device according to any preceding claim wherein said device is provided with identification means.

19. A pouch that is of a size and shape that corresponds to the size and shape of the test device according to any preceding claim.

20. A pouch according to Claim 19 wherein said pouch comprises a desiccant.

21. A pouch according to Claim 20 wherein said desiccant comprises at least a part of at least one surface of said pouch.
22. A pouch according to Claims 20 or 21 wherein said desiccant is provided on an inner surface of said pouch.
23. A pouch according to Claims 20 to 22 wherein said pouch comprises a desiccant surface which is so sized and shaped so that when the test device is inserted into the pouch the supportive material contained in the test device is opposite, or adjacent, the desiccant.
24. A pouch according to Claims 20-23 wherein said desiccant comprises silica gel.
25. A pouch according to Claims 19-24 wherein at least a part of its outer surface is made from impervious material.
26. A test kit comprising at least one test device according to Claims 1 to 18 and at least one pouch according to Claims 19-25.
27. A test kit according to Claim 26 comprising a means for obtaining a sample.
28. A test kit according to Claim 27 wherein said means for obtaining a sample comprises a lance or blade, if a blood sample is required; a pipette if a saliva sample is required; and/or a container if a urine and/or stool sample is required.

29. A test kit according to Claims 26-28 comprising instructions and/or a bar code for identifying purposes.

30. A test kit according to Claim 29 wherein an identification means is provided to indicate the identity and origin of each individual test device, the type of test to be carried out and/or the particular shape of the test device whereby automated testing apparatus can be automatically re-configured following reading of the identification means to accommodate test devices of a variety of shapes and for a variety of tests.

31. A method for confirming the adequacy of a collected fluid sample using the test device according to Claims 1-18, comprising;

(i) providing a substrate of a predetermined size and shape, and including at least one indentation or aperture wherein said indentation or aperture is of a predetermined location, size and shape so as to facilitate handling by an automated testing apparatus; and further comprising a supportative material mounted on at least a part of said substrate so as to be at least partially positioned over said indentation or aperture; wherein said supportative material comprises a guide means characterised by a sample deposition portion and attached thereto a channel portion including an indicator means;

(ii) placing a fluid sample on said sample deposition portion and allowing said fluid sample to fill and/or permeate into said channel portion;

(iii) collecting sufficient fluid of said sample so that said sample passes over said indicator means in or associated with said channel portion;

(iv) assessing said collected fluid sample by visualisation of said indicator means and/or by automated machine analysis of said indicator means.